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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,182	12/17/2001	Elisabeth Stockert	LUD-5466.7 DIV	3379
24972	7590	06/03/2005	EXAMINER	
FULBRIGHT & JAWORSKI, LLP			DAVIS, MINH TAM B	
666 FIFTH AVE			ART UNIT	
NEW YORK, NY 10103-3198			PAPER NUMBER	

1642

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,182

Applicant(s)

STOCKERT ET AL.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32, 34-37, 40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32, 34-37, 40 is/are rejected.
- 7) ☒ Claim(s) 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 32, 34-37, 40-41 are being examined.

The following are the remaining rejections.

It is noted that Applicant arguments, concerning the enablement issue, on page 4, starting at 4th paragraph bridging page 5, are moot, in view that the enablement rejection was not in the prior Office action.

OBJECTION

Claim 41 remains objected to as being dependent upon rejected base claims, but would be allowable if rewritten in independent forms.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

Rejection under 35 USC 112, first paragraph of claims 32, 34-37, 40 pertaining to lack of a clear written description of an immunoreactive portion, remains for reasons already of record in paper of 01/03/05.

Applicant argues that in Lilly, no sequence for human insulin were provided. Applicant argues that peptides that the Examiner finds allowable are described. Applicant argues that Example 12 describes how motifs analysis was carried out using D'Amaro and Drijfhout and that peptides corresponding to all the amino acids deduced

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thereby are synthesized and listed. Applicant argues that SEQ ID NO: 4, 5, 6 are the three best peptides, with respect to binding to HLA-A2 and provoking T cell proliferation.

Applicant argues that if the methodology works for HLA-A2, why would it not work for HLA-A1, -A3, -B7, or -B35, or any MHC molecule.

Applicant argues that a number of T cell epitopes have been identified for peptides with sequences found in SEQ ID NO:1, as found in the attached document.

Applicant's arguments set forth in paper of 04/01/05 have been considered but are not deemed to be persuasive for the following reasons:

The claimed invention does not meet the 112, first paragraph, written description, as shown in the example in Lilly because of the following reasons:

1) The specification does not disclose structural features common to the members of the genus of immunoreactive portions, which features constitute a substantial portion of the genus. There is no correlation between structure and function disclosed for the claimed immunoreactive portions. Although SEQ ID NO:4, 5, 6 are found to bind to HLA-A2 and provoking T cell proliferation, and although several peptides from SEQ ID NO:1 that have HLA binding motifs are disclosed in the specification, there is no common structure among these peptides, and there is no disclosed common structure that is correlated with the ability to complex with an MHC molecule and elicit a T cell response.

2) SEQ ID NO:4, 5, 6 are not representative number of species of the claimed genus immunoreactive portion, because there is no common structure among these peptides.

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Further, it is noted that immunoreactive portion reads on linear and conformational B cell and T cell epitopes. However, the specification has not identified which immunoreactive portions of the peptide encoded by the cDNA fragment of SEQ ID NO:1 have essential characteristics of the claimed linear and conformational B cell and T cell epitopes, other than the three linear peptides of SEQ ID NO:4, 5, 6 that elicit CTL response.

Concerning Applicant's arguments that if the methodology works for HLA-A2, why would it not work for HLA-A1, -A3, -B7, or -B35, or any MHC molecule, the arguments are moot in view that this is a written description rejection and not an enablement rejection.

Concerning Applicant's arguments that a number of T cell epitopes have been identified for peptides with sequences found in SEQ ID NO:1, as found in the attached document, it is noted that the amino acid sequence consisting of the specific peptides cited in the references, which are published after the date of filing of the instant application, are not described in the specification, and one of skill in the art would reasonably conclude that Applicant did not have possession of the claimed genus of immunoreactive portions at the time of filing.

REJECTION UNDER 35 USC 102(b)

Claims 32, 40 remain rejected under 35 USC 102(b) as being anticipated by Morgan et al, 1995, for reasons already of record in paper of 01/03/05.

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Applicant argues that the Examiner has not provided evidence to support the Examiner's position that fragments of 3 amino acids generate B cell response, as discussed in the telephonic interview of 12/14/04.

Applicant's arguments set forth in paper of 04/01/05 have been considered but are not deemed to be persuasive for the following reasons:

The evidence that fragments of 3 amino acids could generate B cell response is not necessary for the 102 rejection, because there is no definition of immunoreactive portion in the specification, and thus the term reads on any reactivity of a portion of the encoded protein with the immune system, wherein this system includes B cells, T cells, Natural killer cells, phagocytes, antigen presenting cells, granulocytes and Platelets etc.. (Roitt I et al, 1993, 3rd ed, Immunology, Mosby, St. Louis, page VI, chapter 2, of record). Any foreign molecule injected into an animal would be recognized by the immune system, and thus be immunoreactive (Stites et al, 1997, supra, page 63, of record).

In addition, although claim 1 is amended to read that the protein comprising the claimed immunoreactive portion is processed by a cell to form a peptide which complexes to an MHC molecule and provides a T cell response, however, the peptide taught by the art is exactly the same as the amino acids 32-34 of the amino acid sequence encoded by SEQ ID NO:1, and thus seems to be the same as the claimed immunoreactive portion of the sequence encoded by SEQ ID NO:1, in view that any foreign molecule injected into an animal would be recognized by the immune system, and thus be immunoreactive, supra.

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Although the reference does not specifically teach an immunoreactive portion of a protein encoded by SEQ ID NO:1, wherein said protein is processed by a cell to form a peptide which complexes to an MHC molecule and provides a T cell response, and wherein the protein is an amino acid sequence of a tumor rejection antigen, however, the claimed immunoreactive portion appears to be the same as the prior art peptide. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

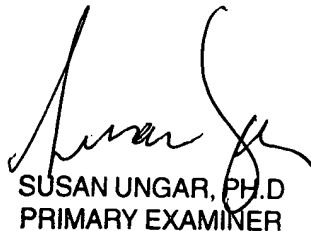
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

May 26, 2005



SUSAN UNGAR, PH.D
PRIMARY EXAMINER